General

Guideline Title

Use of biomarkers to guide decisions on systemic therapy for women with metastatic breast cancer: American Society of Clinical Oncology clinical practice guideline.

Bibliographic Source(s)

Van Poznak C, Somerfield MR, Bast RC, Cristofanilli M, Goetz MP, Gonzalez-Angulo AM, Hicks DG, Hill EG, Liu MC, Lucas W, Mayer IA, Mennel RG, Symmans WF, Hayes DF, Harris LN. Use of biomarkers to guide decisions on systemic therapy for women with metastatic breast cancer: American Society of Clinical Oncology clinical practice guideline. J Clin Oncol. 2015 Aug 20;33(24):2695-704. [49 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the rating of evidence (High, Intermediate, Low, Insufficient); types of recommendations (Evidence based, Formal consensus, Informal consensus, No recommendation); and strength of recommendations (Strong, Moderate, Weak) are provided at the end of the "Major Recommendations" field.

Clinical Question 1

Under what circumstances (i.e., for which patients) should metastases be biopsied or otherwise sampled to test for changes from the primary tumor with respect to endocrine receptor or human epidermal growth factor receptor 2 (HER2) status?

Recommendation 1

At initial presentation of metastasis from breast cancer, it is standard of care to biopsy an accessible lesion to confirm metastatic breast cancer. When evaluating the metastatic site(s), it is important to note that the results of estrogen receptor (ER), progesterone receptor (PR), and/or HER2 status may have changed from the primary tumor, and these results may inform treatment decisions. Therefore, this Panel recommends retesting for ER, PR, and HER2 on ≥ one metastasis with careful attention to assay performance, particularly for bone metastases (see the section "Clinical Interpretation" in the original guideline document). However, for patients with documented changes in these biomarkers, data are lacking to determine whether outcomes from systemic therapy are altered when guided by biomarker test results from the metastases. The Panel informal consensus for the management of care when there is discordance of ER, PR, or HER2 results between primary and metastatic tissues is to use the

ER, PR, or HER2 status from the metastasis to direct therapy, if supported by the clinical scenario and the patient's goals for care. (Type: evidence based for biomarker change from primary to metastasis, but no evidence to demonstrate that systemic therapy choices affect health outcomes when biomarker change occurs. Evidence quality: insufficient. Strength of recommendation: moderate.)

Clinical Question 2

For women with metastatic breast cancer and with known endocrine receptor and HER2 status, which additional tumor markers have demonstrated clinical utility to initiate systemic therapy or direct selection of a new systemic therapy regimen?

Recommendation 2

Decisions concerning the initiation of systemic therapy or selection of systemic therapy for metastatic breast cancer should be guided by ER, PR, and HER2 status, in conjunction with clinical evaluation, judgment, and the patient's goals for care. Presently, there is no evidence that therapy decisions based solely on additional biomarker results improve health outcomes; thus, decisions about initiating or selecting therapy for metastatic breast cancer should be based solely on ER, PR, and HER2 status and the specific clinical scenario. (Type: evidence based. Evidence quality: low. Strength of recommendation: moderate.)

Clinical Question 3

For women with metastatic breast cancer and with known ER, PR, and HER2 status, which additional tumor markers have demonstrated clinical utility to guide decisions on switching to a different drug or regimen or discontinuing treatment?

Recommendation 3

Recommendations for Tissue Biomarkers

In patients who are already receiving systemic therapy for metastatic breast cancer, decisions on changing to a new drug or regimen or discontinuing treatment should be based on the patient's goals for care and clinical evaluation and judgment of disease progression or response, given that there is no evidence at this time that changing therapy solely on the basis of biomarker results beyond ER, PR, and HER2 improves health outcome, quality of life, or cost effectiveness. (Type: evidence based. Evidence quality: low. Strength of recommendation: moderate.)

Recommendations for Circulating Tumor Markers

In patients already receiving systemic therapy for metastatic breast cancer, decisions on changing to a new drug or regimen or discontinuing treatment should be based on the patient's goals for care and clinical evaluation and judgment of disease progression or response, given that there is no evidence at this time that changing therapy solely on the basis of circulating biomarker results improves health outcome, quality of life, or cost effectiveness. (Type: evidence based. Evidence quality: intermediate. Strength of recommendation: moderate.)

Carcinoembryonic antigen (CEA), cancer antigen (CA) 15-3, and CA 27-29 may be used as adjunctive assessments to contribute to decisions regarding therapy for metastatic breast cancer. Data are insufficient to recommend use of CEA, CA 15-3, and CA 27-29 alone for monitoring response to treatment. The Panel acknowledges the lack of evidence of clinical utility in support of use of these circulating biomarkers; biochemical assessments of CEA, CA 15-3, and CA 27-29 were developed before the present standards for measuring clinical utility. The recommendation for use is based on clinical experience and Panel informal consensus in the absence of studies designed to evaluate the clinical utility of the markers. As such, it is also reasonable for clinicians to not use these markers as adjunctive assessments. (Type: informal consensus. Evidence quality: insufficient. Strength of recommendation: moderate.)

Clinical Question 4

For biomarkers shown to have clinical utility to guide decisions on systemic therapy for metastatic disease in questions 2 and 3, what are the appropriate assays, timing, and frequency of measurement?

Recommendation 4

Decisions for systemic therapy should be influenced by ER, PR, and HER2. The American Society of Clinical Oncology (ASCO) recently updated the guideline addressing optimization of HER2 assays. To date, clinical utility has not been demonstrated for any additional biomarkers. (Type: informal consensus. Evidence quality: low. Strength of recommendation: strong.)

Definitions

Guide for Rating Strength of Evidence

Rating for Strength of Evidence	Definition
High	High confidence that the available evidence reflects the true magnitude and direction of the net effect (i.e., balance of benefits versus harms) and further research is very unlikely to change either the magnitude or direction of this net effect.
Intermediate	Moderate confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research is unlikely to alter the direction of the net effect; however, it might alter the magnitude of the net effect.
Low	Low confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research may change either the magnitude and/or direction this net effect.
Insufficient	Evidence is insufficient to discern the true magnitude and direction of the net effect. Further research may better inform the topic. The use of the consensus opinion of experts is reasonable to inform outcomes related to the topic.

Guide for Rating of Potential for Bias

Rating of Potential for Bias	Definitions for Rating Potential for Risk of Bias in Randomized Controlled Trials
Low risk	No major features in the study that risk biased results, and none of the limitations are thought to decrease the validity of the conclusions. The study avoids problems such as failure to apply true randomization, selection of a population unrepresentative of the target patients, high dropout rates, and no intention-to-treat analysis; and key study features are described clearly (including the population, setting, interventions, comparison groups, measurement of outcomes, and reasons for dropouts).
Intermediate	The study is susceptible to some bias, but flaws are not sufficient to invalidate the results. Enough of the items introduce some uncertainty about the validity of the conclusions. The study does not meet all the criteria required for a rating of good quality, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems.
High risk	There are significant flaws that imply biases of various types that may invalidate the results. Several of the items introduce serious uncertainty about the validity of the conclusions. The study has serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.

Guide for Types of Recommendations

Type of Recommendation	Definition
Evidence based	There was sufficient evidence from published studies to inform a recommendation to guide clinical practice.
Formal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. Therefore, the expert Panel used a formal consensus process to reach this recommendation, which is considered the best current guidance for practice. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak"). The results of the formal consensus process are summarized in the guideline and reported in an online data supplement (see the "Availability of Companion Documents" field).
Informal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. The recommendation is considered the best current guidance for practice, based on informal consensus of the Expert Panel. The Panel agreed that a formal consensus process was not necessary for reasons described in the literature review and discussion. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak").
No recommendation	There is insufficient evidence, confidence, or agreement to provide a recommendation to guide clinical practice at this time. The Panel deemed the available evidence as insufficient and concluded it was unlikely that a formal consensus process would achieve the level of agreement needed for a recommendation.

Guide for Strength of Recommendations

Rating for Strength of Recommendation	Definition

Rating for Strength of Recommendation	Definition
Strong	There is high confidence that the recommendation reflects best practice. This is based on (1) strong evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with no or minor exceptions; (3) minor or no concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a strong recommendation.
Moderate	There is moderate confidence that the recommendation reflects best practice. This is based on (1) good evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with minor and/or few exceptions; (3) minor and/or few concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a moderate recommendation.
Weak	There is some confidence that the recommendation offers the best current guidance for practice. This is based on (1) limited evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, but with important exceptions; (3) concerns about study quality; and/or (4) the extent of panelists' agreement. Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Metastatic breast cancer

Guideline Category

Diagnosis

Management

Clinical Specialty

Oncology

Pathology

Radiation Oncology

Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Guideline Objective(s)

To provide recommendations on the appropriate use of breast tumor biomarker assay results to guide decisions on systemic therapy for metastatic breast cancer

Target Population

Women with metastatic breast cancer being considered for systemic therapy or for changes in the drug or regimen they are receiving

Interventions and Practices Considered

1. Biopsy of accessible lesion
2. Testing of metastatic tumor for estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) status
3. Use of circulating tumor markers (carcinoembryonic antigen [CEA], cancer antigen [CA] 15-3, and CA 27-29) as adjunctive assessments
4. Decisions on systemic therapy based on clinical evaluation, judgment of disease progression or response, and the patient's goals for care

Major Outcomes Considered

- Disease-free survival
- Adverse effects of therapy
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Strategy

The Expert Panel developed its recommendations based on evidence identified through online searches of Medline and the Cochrane Library (from January 2006 through August 2014, to overlap with the search end date for the 2007 guideline update on tumor markers in breast cancer [Harris et al., 2007]), and their own clinical experience. See Data Supplement 3 (see the "Availability of Companion Documents" field) for full details on the search string. A combined PubMed search was conducted for this guideline and for a similar guideline on use of biomarkers to guide decisions on systemic therapy in metastatic breast cancer, with articles selected for each guideline's systematic review based on the patient population studied. Articles were selected for inclusion in the systematic review based on the following criteria:

Population: Women with metastatic breast cancer being considered for initiation of systemic therapy, or for changes in the drug or regimen they are receiving, with separate sub-questions and analyses on patient groups with:

- Endocrine receptor positive disease
- Human epidermal growth factor receptor 2 (HER2), positive disease
- Triple negative disease
- And on use of tumor marker assay results to guide decisions on:
- First-line therapy
- Second- or subsequent-line therapy

Publications in English were included if they reported rigorously conducted systematic reviews (with or without meta-analyses), randomized controlled trials (RCTs), retrospective biomarker analyses of samples from completed prospective RCTs, or prospective observational studies that directly compared outcomes of treatment decisions made on the basis of assay results with outcomes of treatment decisions made regardless of assay results.

Articles were excluded from the systematic review if they were (1) meeting abstracts not subsequently published in peer-reviewed journals; (2) editorials, commentaries, letters, news articles, case reports, narrative reviews; (3) published in a non-English language; (4) retrospective observational studies.

Number of Source Documents

The literature search revealed 17 articles that met criteria for further review: 11 studies reporting discordances between primary tumors and metastases in expression of hormone receptors or human epidermal growth factor receptor 2 (HER2), one randomized controlled trial (RCT) that addressed the use of a biomarker to decide whether to change or continue a treatment regimen, and five prospective-retrospective studies that evaluated the clinical utility of biomarkers.

Also see Data Supplement 2 (see the "Availability of Companion Documents" field) for a Quality of Reporting of Meta-analyses (QUOROM) Diagram showing exclusions and inclusions of publications identified for the systematic review.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Guide for Rating Strength of Evidence

Rating for Strength of Evidence	Definition
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Low	Low confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research may change either the magnitude and/or direction this net effect.
Insufficient	Evidence is insufficient to discern the true magnitude and direction of the net effect. Further research may better inform the topic. The use of the consensus opinion of experts is reasonable to inform outcomes related to the topic.

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Intermediate	The study is susceptible to some bias, but flaws are not sufficient to invalidate the results. Enough of the items introduce some uncertainty about the validity of the conclusions. The study does not meet all the criteria required for a rating of good quality, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems.
High risk	There are significant flaws that imply biases of various types that may invalidate the results. Several of the items introduce serious uncertainty about the validity of the conclusions. The study has serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction

Literature search results were reviewed and deemed appropriate for full text review by an American Society of Clinical Oncology (ASCO) staff member, in consultation with the Expert Panel Co-Chairs. Data were extracted by one reviewer.

Data Supplements 3 and 4 (see the "Availability of Companion Documents" field) include results of data extraction from the literature review. Data Supplement Tables 2 through 7 provide information on key characteristics of the studies and their patient populations, on study quality assessment, and on reported outcomes. None of the included studies reported on toxicity, either of biomarker testing or of systemic therapy, for patient subgroups subdivided biomarker results. In addition, no studies reported on changes in quality-of-life outcomes attributable to biomarker testing.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Panel Composition

The American Society of Clinical Oncology (ASCO) Clinical Practice Guidelines Committee (CPGC) and the ASCO Breast Cancer Guideline Advisory Group (GAG) convened an Expert Panel with multidisciplinary representation in medical oncology, radiation oncology, and community oncology, statistician, health outcome researchers, the Practice Guidelines Implementation Network, and patient/advocacy representation. The Expert Panel was led by two Co-Chairs who had the primary responsibility for the development and timely completion of the guideline. The Panel had one face-to-face meeting and three webinars. The Co-Chairs and ASCO staff prepared a draft guideline for review and rating by the Expert Panel. The Expert Panel members are listed in Appendix Table A1 of the original guideline document.

Guideline Development Process

The Expert Panel met on several occasions and corresponded frequently through email; progress on guideline development was driven primarily by the Co-Chairs and ASCO staff. The purpose of the Panel meetings was for members to contribute content, provide critical review, interpret evidence, and finalize the guideline recommendations based upon the consideration of the evidence. All members of the Expert Panel participated in the preparation of the draft guideline document, which was then disseminated for external review and submitted to the *Journal of Clinical Oncology* (*JCO*) for peer review and publication.

Development of Recommendations

The guideline recommendations were crafted, in part, using the principles of the GuideLines Into DEcision Support (GLIDES) methodology. This method helps guideline panels systematically develop clear, translatable, and implementable recommendations using natural language, based on the evidence and assessment of its quality, to increase usability for end users. The process incorporates distilling the actions involved, identifying who will carry them out, to whom, under what circumstances, and clarifying if and how end users can carry out the actions consistently. This process helps the Panel focus the discussion, avoid using unnecessary and/or ambiguous language, and clearly state its intentions.

Rating Scheme for the Strength of the Recommendations

Guide for Types of Recommendations

Type of Recommendation	Definition
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Informal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. The recommendation is considered the best current guidance for practice, based on informal consensus of the Expert Panel. The Panel agreed that a formal consensus process was not necessary for reasons described in the literature review and discussion. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak").
No recommendation	There is insufficient evidence, confidence, or agreement to provide a recommendation to guide clinical practice at this time. The Panel deemed the available evidence as insufficient and concluded it was unlikely that a formal consensus process would achieve the level of agreement needed for a recommendation.

Guide for Strength of Recommendations

Rating for Strength of Recommendation	Definition
Strong	There is high confidence that the recommendation reflects best practice. This is based on (1) strong evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with no or minor exceptions; (3) minor or no concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a strong recommendation.
Moderate	There is moderate confidence that the recommendation reflects best practice. This is based on (1) good evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with minor and/or few exceptions; (3) minor and/or few concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a moderate recommendation.
Weak	There is some confidence that the recommendation offers the best current guidance for practice. This is based on (1) limited evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, but with important exceptions; (3) concerns about study quality; and/or (4) the extent of panelists' agreement. Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

All members of the Expert Panel participated in the preparation of the draft guideline document, which was then disseminated for external review and submitted to the *Journal of Clinical Oncology* (*JCO*) for peer review and publication. All American Society of Clinical Oncology (ASCO) guidelines are reviewed and approved by the ASCO Clinical Practice Guidelines Committee (CPGC) prior to publication.

The CPGC approved this guideline on January 21, 2015.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

A biomarker-based test is judged to have clinical utility if use of the test is demonstrated to result in a favorable balance of benefits to harms. If clinical care options result in similar patient survival, biomarker tests may still have clinical utility if they direct care to options that result in improved quality of life (e.g., less toxicity or inconvenience) or lower cost. A new biomarker test must be shown to contribute clinically useful information beyond that already provided by standardly used clinical or pathologic indicators, unless the new test can provide equivalent information at a lower cost, less invasively, or with less inconvenience or risk.

Potential Harms

- For needle biopsies of metastatic breast cancer to bone, submitting the accompanying blood clot in the specimen container separately from the fragments of bony tissue may yield viable tumor that would not have to undergo decalcification and could be used for the analysis of human epidermal growth factor receptor 2 (HER2) in breast cancer metastatic to skeletal tissue. If it is not possible to test a sample that has not undergone decalcification, a negative result should be interpreted with caution, and consideration should be given to an additional and more suitable biopsy sample for testing.
- Caution should be used when interpreting increasing carcinoembryonic antigen (CEA), cancer antigen (CA) 15-3, or CA 27-29 level during the first 4 to 6 weeks of administration of a new therapy, given that spurious early increases may occur.
- There have been reports of liver and renal dysfunction affecting the values of serum tumor markers, which demonstrates that multiple chronic conditions (MCCs) may confuse the interpretation of serum tumor markers. There is insufficient evidence to calibrate how MCCs may affect the results of biomarker testing.

Qualifying Statements

Qualifying Statements

- The clinical practice guideline and other guidance published herein are provided by the American Society of Clinical Oncology (ASCO) to assist providers in clinical decision making. The information herein should not be relied on as being complete or accurate, nor should it be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. With the rapid development of scientific knowledge, new evidence may emerge between the time information is developed and when it is published or read. The information is not continually updated and may not reflect the most recent evidence. The information addresses only the topics specifically identified herein and is not applicable to other interventions, diseases, or stages of diseases. This information does not mandate any particular course of medical care. Furthermore, the information is not intended to substitute for the independent professional judgment of the treating provider, because the information does not account for individual variation among patients. Recommendations reflect high, moderate, or low confidence that the recommendation reflects the net effect of a given course of action. The use of words like "must," "must not," "should," and "should not" indicates that a course of action is recommended or not recommended for either most or many patients, but there is latitude for the treating physician to select other courses of action in individual cases. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. ASCO provides this information on an as-is basis and makes no warranty, express or implied, regarding the information. ASCO specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. ASCO assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information or for any errors or omissions.
- Refer to the "Health Disparities" and "Limitations of the Research" sections in the original guideline document for additional qualifying information.

Implementation of the Guideline

Description of Implementation Strategy

American Society of Clinical Oncology (ASCO) guidelines are developed for implementation across health settings. Barriers to implementation include the need to increase awareness of the guideline recommendations among front-line practitioners and survivors of cancer and caregivers and also to provide adequate services in the face of limited resources. The guideline Bottom Line Box was designed to facilitate implementation of recommendations. This guideline will be distributed widely through the ASCO Practice Guideline Implementation Network. ASCO guidelines are posted on the ASCO Web site and usually published in *Journal of Clinical Oncology* (*JCO*) and *Journal of Oncology Practice*.

For information on the ASCO implementation strategy, please see the ASCO Web site .

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Van Poznak C, Somerfield MR, Bast RC, Cristofanilli M, Goetz MP, Gonzalez-Angulo AM, Hicks DG, Hill EG, Liu MC, Lucas W, Mayer IA, Mennel RG, Symmans WF, Hayes DF, Harris LN. Use of biomarkers to guide decisions on systemic therapy for women with metastatic breast cancer: American Society of Clinical Oncology clinical practice guideline. J Clin Oncol. 2015 Aug 20;33(24):2695-704. [49 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Aug 20

Guideline Developer(s)

American Society of Clinical Oncology - Medical Specialty Society

Source(s) of Funding

American Society of Clinical Oncology (ASCO)

Guideline Committee

Expert Panel

Composition of Group That Authored the Guideline

Expert Panel Members: Lyndsay N. Harris, MD (*Co-chair*), Seidman Cancer Center, Case Western Reserve University, Cleveland, OH; Catherine Van Poznak, MD (*Co-chair, Practice Guideline Implementation Network [PGIN] representative*), University of Michigan Comprehensive Cancer Center, Ann Arbor, MI; Robert C. Bast, MD, University of Texas MD Anderson Cancer Center, Houston, TX; Massimo Cristofanilli, MD, Thomas Jefferson University–Kimmel Cancer Center, Philadelphia, PA; Elizabeth G. Hill, PhD, Medical University of South Carolina, Hollings Cancer Center, Charleston, SC; Matthew P. Goetz, MD, Mayo Clinic, Rochester, MN; Daniel F. Hayes, MD, University of Michigan Comprehensive Cancer Center, Ann Arbor, MI; David G. Hicks, MD, University of Rochester Medical Center, Rochester, NY; Minetta C. Liu, MD, Mayo Clinic, Rochester, MN; Wanda Lucas, MBA (*Patient representative*), Georgetown University, Washington, DC; Ingrid A. Mayer, MD, MSCI Vanderbilt University Medical Center and Vanderbilt-Ingram Cancer Center, Nashville, TN; Robert G. Mennel, MD, Texas Oncology, Dallas, TX; William F. Symmans, MD, University of Texas MD Anderson Cancer Center, Houston, TX

Financial Disclosures/Conflicts of Interest

The Expert Panel was assembled in accordance with the American Society of Clinical Oncology (ASCO) Conflicts of Interest Management Procedures for Clinical Practice Guidelines (summarized at http://www.asco.org/rwc). Members of the Panel completed the ASCO disclosure form, which requires disclosure of financial and other interests that are relevant to the subject matter of the guideline, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the guideline. Categories for disclosure include employment; leadership; stock or other ownership; honoraria, consulting, or advisory role; speaker's bureau; research funding; patents, royalties, or other intellectual property; expert testimony; travel, accommodations, or expenses; and other relationships. In accordance with these procedures, the majority of the members of the Panel did not disclose any such relationships. Notably, one author (D.F.H.) recused himself from deliberations and Panel votes concerning recommendations for circulating tumor cells (CTCs) because of potential conflicts of interest.

Authors' Disclosures of Potential Conflicts of Interest

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated. Relationships are self-held unless noted. I=Immediate Family Member, Inst=My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to www.asco.org/rwc or jco.ascopubs.org/site/ifc .

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Research Funding: Amgen (Inst), Novartis (Inst)
Patents, Royalties, Other Intellectual Property: UpToDate

Mark R. Somerfield
No relationship to disclose

Robert C. Bast
Research Funding: Arrian Pharmaceuticals
Patents, Royalties, Other Intellectual Property: Fujirebio Diagnostics

Massimo Cristofanilli
Honoraria: Agendia, Dompe, Cynvenio, NanoString Technologies
Consulting or Advisory Role: Dompe, Cynvenio, Newomics
Speakers' Bureau: Agendia, NanoString Technologies

Elizabeth G. Hill
Consulting or Advisory Role: Apogee Biotechnology Corporation

Matthew P. Goetz
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Travel, Accommodations, Expenses: Eli Lilly

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Stock or Other Ownership: MedFusion

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Stock or Other Ownership: Amgen, ISIS Pharmaceuticals, Nuvera Biosciences
Honoraria: Orlando Health
Patents, Royalties, Other Intellectual Property: Patent for the formula to calculate residual cancer burden after neoadjuvant chemotherapy; patent pending for genomic signatures of estrogen receptor–related gene expression and for prediction of response and survival from adjuvant chemotherapy and/or endocrine therapy
Travel, Accommodations, Expenses: Affymetrix, Celgene

Daniel F. Hayes
Stock or Other Ownership: Oncimmune, Inbiomotion
Honoraria: Third UK Breast Cancer Meeting, London, Lilly Oncology
Consulting or Advisory Role: Pfizer
Research Funding: Janssen R&D (Johnson & Johnson parent company) (Inst), AstraZeneca (Inst), Puma Biotechnology (Inst), Pfizer (Inst)
Patents, Royalties, Other Intellectual Property: Title: A method for predicting progression free and overall survival at each follow-up timepoint during therapy of metastatic breast cancer patients using circulating tumor cells; patent No. 05725638.0-1223-US2005008602; Title: Diagnosis and treatment of breast cancer; original application No. 61/079, 642; revised application No. 61/224, 310; Title: Circulating tumor cell capturing techniques and devices; original application No. 61/593, 092; royalties from licensed technology

Lyndsay N. Harris
No relationship to disclose

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Journal of Clinical Oncology Web site .

Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 2318 Mill Rd, Suite 800, Alexandria, VA 22314; E-mail: guidelines@asco.org.

Availability of Companion Documents

The following are available:

- Use of biomarkers to guide decisions on systemic therapy for women with metastatic breast cancer: American Society of Clinical Oncology clinical practice guideline. Methodology supplement. Alexandria (VA): American Society of Clinical Oncology; 2015. 6 p. Available from the American Society of Clinical Oncology (ASCO) Web site .
- Use of biomarkers to guide decisions on systemic therapy for women with metastatic breast cancer: American Society of Clinical Oncology clinical practice guideline. Data supplements 1-5. Alexandria (VA): American Society of Clinical Oncology; 2015. 28 p. Available from the ASCO Web site .
- Use of biomarkers to guide decisions on systemic therapy for women with metastatic breast cancer: American Society of Clinical Oncology clinical practice guideline. Slide set. Alexandria (VA): American Society of Clinical Oncology; 2015. Available in PDF and PowerPoint from the ASCO Web site.
- Use of biomarkers to guide decisions on systemic therapy for women with metastatic breast cancer: American Society of Clinical Oncology clinical practice guideline. Summary of recommendations. Alexandria (VA): American Society of Clinical Oncology; 2015. 3 p. Available from the ASCO Web site .

Patient Resources

The following is available:

- Biomarkers to guide treatment for metastatic breast cancer. Patient information. 2015 Jul 20. Available from the Cancer.Net Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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